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(54) **METHOD OF TREATING SCOLIOSIS USING A BIOLOGICAL IMPLANT**

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(60) Provisional application No. 60/622,999, filed on Oct. 28, 2004, provisional application No. 61/073,119, filed on Jun. 17, 2008, provisional application No. 61/082,503, filed on Jul. 21, 2008, provisional application No. 60/806,498, filed on Jul. 3, 2006, provisional application No. 60/825,260, filed on Sep. 11, 2006.

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(58) **Field of Classification Search** 606/60, 606/246, 279, 914; 623/17.11–17.16
See application file for complete search history.

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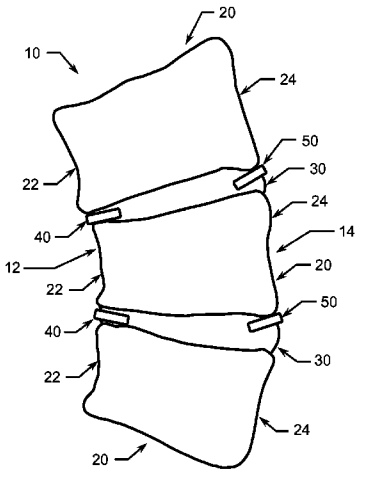
(57) **ABSTRACT**

The present invention is a bone growth stimulating and promoting cytokine type biological implant preferably comprising PTH coated with a controlled release biodegradable coating that is implanted preferably in the concave side of a scoliotically curved spine in combination with a bone growth inhibiting type biological implant preferably comprising methotrexate or like anti-metabolite coated with a controlled release biodegradable coating that is implanted preferably in the convex side of a scoliotically curved spine. The insertion of the biological implant is highly non-invasion, especially as compared to more conventional spine surgical methods, and the biological implant does not decrease spinal mobility or spinal range of motion.

51 Claims, 2 Drawing Sheets



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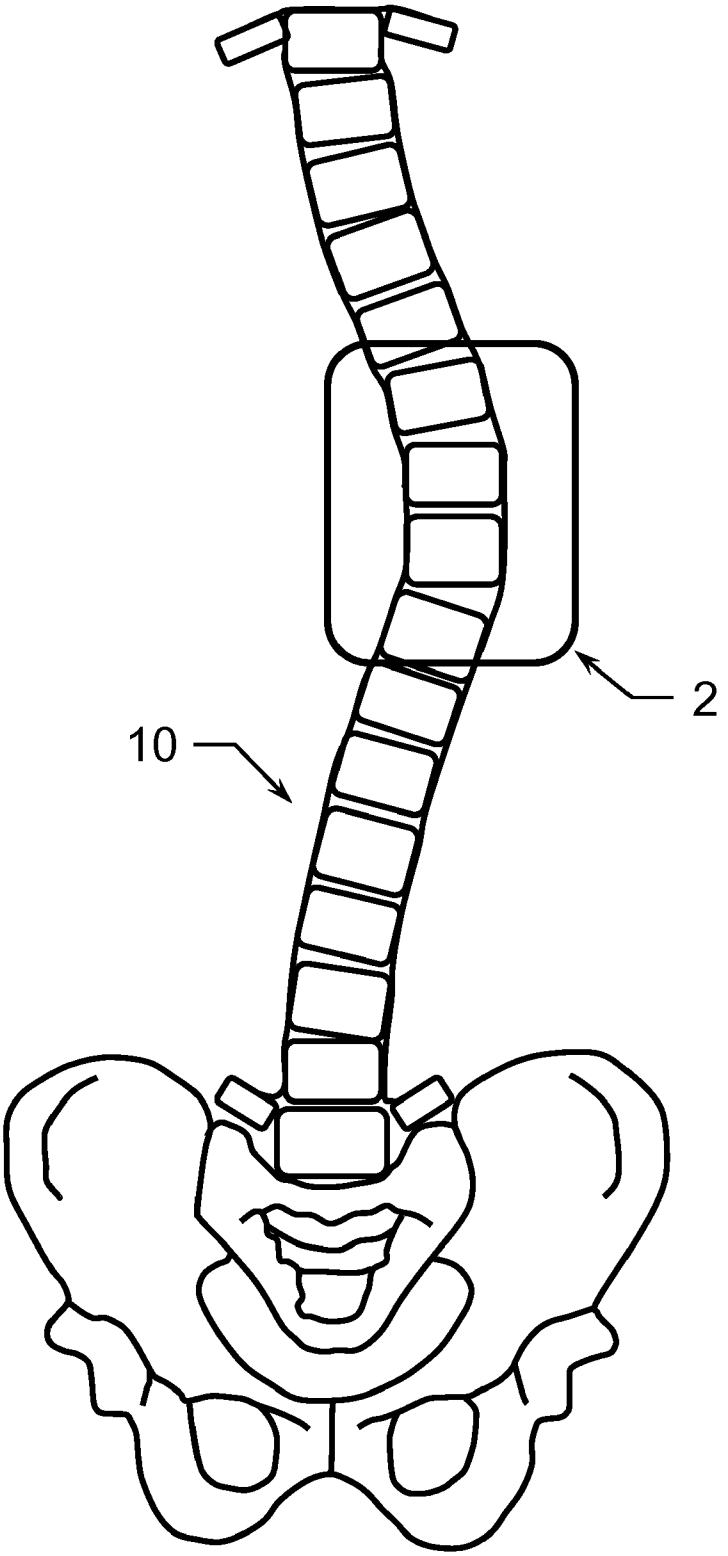

Figure 1

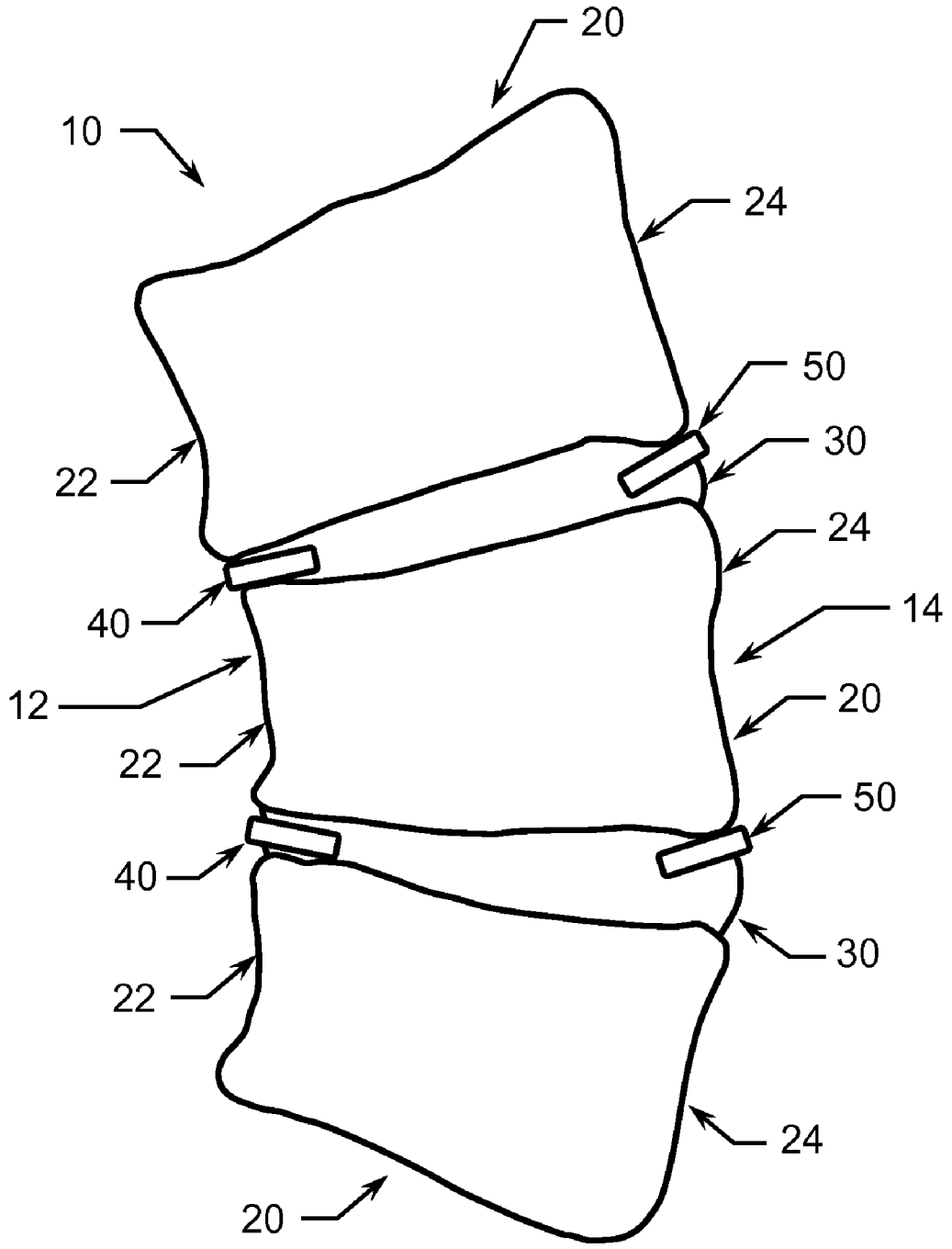

Figure 2

METHOD OF TREATING SCOLIOSIS USING A BIOLOGICAL IMPLANT

CROSS REFERENCE TO RELATED APPLICATIONS

This nonprovisional utility application is a continuation-in-part of and claims the benefit under 35 USC §120 to co-pending U.S. application Ser. No. 11/259,941 filed Oct. 26, 2005 which claims the benefit under 35 USC §119(e) of U.S. Provisional Application No. 60/622,999, filed Oct. 28, 2004, and the instant application claims the benefit under 35 USC §119(e) to U.S. Provisional Application No. 61/073,119, filed Jun. 17, 2008, and claims the benefit under 35 U.S.C. §119(e) to U.S. Provisional Application No. 61/082,503, filed Jul. 21, 2008, and is a continuation-in-part of and claims the benefit under 35 U.S.C. §120 to co-pending U.S. application Ser. No. 11/968,046, filed Dec. 31, 2007 and is a continuation of and claims the benefit under 35 U.S.C. §365(c) of International Patent Application No. PCT/US07/72785 with an international filing date of Jul. 3, 2007 which claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Application No. 60/806,498, filed Jul. 3, 2006, and of U.S. Provisional Patent Application No. 60/825,260, filed Sep. 11, 2006, all of which are incorporated, in their entirety, by this reference.

FIELD OF THE INVENTION

The present invention relates to the management of bone growth, and more especially management of bone growth to correct for skeletal deformities such as scoliosis through the selective use of biological implants.

BACKGROUND OF THE INVENTION

Scoliosis, a medical condition in humans typically characterized by the side-to-side or lateral curvature of the spine, is a common problem affecting more than 2 percent of the US population. Further other related skeletal problems are also common in the human population. Many inventions have been directed to therapeutics for the prevention and correction of scoliosis and like conditions. Such therapeutics include for instance corrective bracing, corrective surgery and certain exercise routines. Certain instances of such therapeutics have shown greater effectiveness than others. In the case of corrective surgery, such therapeutic may prove highly effective in correcting scoliosis but typically is relatively invasive and potentially traumatic to the patient, and may result in the loss of mobility and range of motion of the spine. Accordingly, there exists a need to for a preventative and corrective scoliosis therapeutic that is highly minimally invasive and does not reduce the patient's mobility and range of motion.

SUMMARY OF THE INVENTION

The present invention therefore is a method and apparatus for bone growth management using biological implants. In an embodiment of the invention, a first implant defines a bone growth stimulating and promoting cytokine type biological implant such as Parathyroid hormone (PTH) having a controlled release or controlled time dissolvable biodegradable coating, and a second implant defines a bone growth inhibiting type biological implant such as a composition that includes as at least a portion thereof methotrexate or like anti-metabolite and having a controlled release or controlled time dissolvable biodegradable coating. The first implant is preferably inserted between vertebra, near a growth plate, on the concave side of a scoliotically curved spine by means of inserting the tip of a trocar into the desired area of the spine, and passing the implant through the trocar and into the desired area of the spine of a patient. The second implant is preferably inserted between vertebra, near a growth plate, on the convex side of a scoliotically curved spine by means of inserting the tip of a trocar into the desired area of the spine, and passing the implant through the trocar and into the desired area of the spine of a patient. After implant insertion and over the course of time, the implants dissolve releasing the bone growth simulating cytokine and the bone growth inhibiting composition to the vertebra. In response, the vertebra grows a greater amount on a concave side of the spine than on a convex side of the spine. This asymmetric growth of the spine over time causes the spine to transition from a substantially scoliotically curved configuration to a substantially non-scoliotically curved configuration.

DESCRIPTION OF DRAWINGS

In order that the advantages of the invention will be readily understood, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments that are illustrated in the appended drawings. Understanding that these drawings depict only typical embodiments of the invention and are not therefore to be considered to be limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings, in which:

FIG. **1** is a substantially orthographic anterior/posterior schematic view of a scoliotic spine, and;

FIG. **2** is a close-up schematic view of a portion of the spine shown in FIG. **1**.

DETAILED DESCRIPTION OF THE INVENTION

Reference throughout this specification to "one embodiment," "an embodiment," or similar language means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention. Thus, appearances of the phrases "in one embodiment," "in an embodiment," and similar language throughout this specification may, but do not necessarily, all refer to the same embodiment.

Furthermore, the described features, structures, or characteristics of the invention may be combined in any suitable manner in one or more embodiments. In the following description, numerous specific details are included to provide a thorough understanding of embodiments of the invention. One skilled in the relevant art will recognize, however, that the invention can be practiced without one or more of the specific details, or with other methods, components, materials, and so forth. In other instances, well-known structures, materials, or operations are not shown or described in detail to avoid obscuring aspects of the invention.

It is known that growth of the physeal plate results in longitudinal growth of long bones. In the spine, increase in height of vertebral bodies is accomplished through growth of the cartilaginous endplate. Growth of the physeal plate is influenced by both mechanical factors and signaling molecules. Stimulation of physeal chondrocytes growth is controlled through a complex interaction of local and systemic pathways. Many cytokines (a category of signaling proteins) have an anabolic effect of growth plate cartilage.

Specifically it is known that Parathyroid hormone (PTH) stimulates physeal chondrocytes. The overall effect of PTH

on the growth plate chondrocyte appears to be a stimulation of proteoglycan synthesis that is mediated by the degradation products of membrane phosphoinositides.

It is known that Fibroblast growth factors can stimulate growth of the physeal plate. In chick growth plate chondrocytes tritiated thymidine incorporation was increased 11-fold by fibroblast growth factor (10 ng/ml) and 3.5 by TGF-beta. Studies have identified FGF18 as a selective ligand for FGFR3 in limb bud mesenchymal cells, which suppressed proliferation and promoted their differentiation and production of cartilage matrix. Research work has identified FGF18 and FGFR3 as potential molecular targets for intervention in tissue engineering aimed at cartilage repair and regeneration of damaged cartilage.

Furthermore, it is know that androgens have an anabolic effect, and it is known that Insulin-like Growth Factors (IGF), Estrogens, and Transforming Growth Factors (TGF), all stimulate growth. Calcium metabolism has an influence on growth plate activity. Inorganic phosphate may act as a signaling molecule in the regulation of bone formation. All of the above listed cytokines may be incorporated in the form of a biological implant.

Furthermore, it is known that methotrexate or like anti-metabolites function to inhibit bone growth. Methotrexate or like anti-metabolite may be incorporated in the form of a biological implant.

The biological implant is preferably coated with a timed release or time dissolvable biodegradable coating. Such coatings are commercially available for instance from the SurModics Corporation and sold under various trademarked names such as SynBiosys, Eureka and PolyActive. The implant may be shaped for instance in the form of a cylinder with rounded or hemispherically shaped ends. Alternatively, the implant may be preformed to adapt to a particular implantation target site, for instance a surface of the implant may be shaped to form to the shape of a portion of a vertebra. Further alternatively, the implant may be somewhat compliant so as to be at least partially pressed into a shaped that conforms to a target site such as to the shape of a portion of a vertebra.

In order to facilitate the understanding of the present invention in reviewing the drawings accompanying the specification, a feature list is provided below. It is noted that like features are like numbered throughout all of the figures.

FEATURE TABLE

#	Feature
10	Scoliotic vertebrae or spine
12	Scoliotic vertebrae concave side
14	Scoliotic vertebrae convex side
20	Scoliotic vertebra
22	Scoliotic vertebra concave side
24	Scoliotic vertebra convex side
30	Spinal disk
40	Biological implant - bone growth promoting
50	Biological implant - bone growth inhibiting

Referring now to the drawings, the invention is a first bone growth stimulating and promoting cytokine type biological implant **40** comprising PTH coated with a controlled release biodegradable coating that is implanted preferably in close proximity to a concave side **12** of a scoliotically curved spine **10**, and a second bone growth inhibiting type biological implant **50** comprising a bone growth inhibiting composition such as methotrexate coated with a controlled release biodegradable coating that is implanted preferably in close proximity to a convex side **14** of a scoliotically curved spine **10**. More specifically, implant **40** is preferably implanted between a concave side **22** of a first scoliotic vertebra **20** and a concave side **22** of a second scoliotic vertebra **20**, so as to be in near proximity to at least one growth plate of vertebra **20** and so as to be in near proximity to disk **30** and implant **50** is preferably implanted between a convex side **24** of a first scoliotic vertebra **20** and a concave side **24** of a second scoliotic vertebra **20**, so as to be in near proximity to at least one growth plate of vertebra **20** and so as to be in near proximity to disk **30**. Alternatively, it is noted however, that rather than both bone growth promoting implant **40** and bone growth inhibiting implant **50** being used in combination, bone growth promoting implant **40** may be used without bone growth inhibiting implant **50**, and bone growth inhibiting implant **50** may be used without bone growth promoting implant **40**. First biological implant **40** is preferably inserted between a first vertebra **20** and a second vertebra **20** on concave side **12** of scoliotically curved spine **10** by means of inserting the tip of a trocar into the desired area of concave side **12** of scoliotically curved spine **10**, and passing implant **40** through the trocar and into the desired area of scoliotically curved spine **10** of a patient. Second biological implant **50** is preferably inserted between a first vertebra **20** and a second vertebra **20** on convex side **14** of scoliotically curved spine **10** by means of inserting the tip of a trocar into the desired area of convex side **14** of scoliotically curved spine **10**, and passing implant **50** through the trocar and into the desired area of scoliotically curved spine **10** of a patient. Such insertion of biological implants **40** and **50** is highly non-invasive, requiring only small incisions, as compared to more conventional spine surgical methods which require large and invasive surgical cuts. Further, the insertion of such biological implants **40** and **50** does not decrease spinal mobility or spinal range of motion. Over the course of time, the implants **40** and **50** dissolve releasing the bone growth simulating cytokine and/or the bone growth inhibiting anti-metabolite or functional equivalent to vertebrae **10**. In response to such implantation, vertebrae **10** grows a greater amount on concave side **12** of the vertebrae **10** than on convex side **14** of vertebrae **10**. The asymmetric growth of vertebrae **10** over time causes vertebrae **10** to transition from a substantially scoliotically curved configuration to a substantially non-scoliotically curved configuration.

It is noted that the disclosed invention is preferably practiced in combination with a screening test that screens patients for a predisposition to scoliosis, and more especially, that screens scoliosis patients for a predisposition to scoliosis curve progression. Such scoliosis and scoliosis curve progression screening is disclosed in U.S. patent application Ser. Nos. 60/806,498, 60/825,260, 60/825,249, 60/862,276, 11/968,046, 11/968,074, 12/024,495, and 61/082,503 the whole of which are incorporated herein by reference. Thus by means of employing such screening, the method and apparatus for bone growth management using a biological implant as disclosed herein, is preferably only practiced on those patients who are determined to be at risk for scoliosis curve development or progression.

It is noted that the disclosed invention may further be practiced in combination with applying a brace to the patient. An exemplary brace for the treatment of scoliosis preferably used in combination with the method and apparatus for bone growth management using a biological implant as disclosed herein is disclosed in U.S. patent application Ser. No. 12/145,959, the whole of which is incorporated herein by reference.

It is noted that the disclosed invention may further be practiced in combination with preferably minimally invasive

non-biological implants for the correction of a scoliotically curved spine. An exemplary non-biological implant for the treatment of scoliosis preferably used in combination with the method and apparatus for bone growth management using a biological implant as disclosed herein is disclosed in U.S. patent application Ser. No. 11/259,941 which the current application is a continuation-in-part thereof, and the whole of which is incorporated herein by reference.

It is noted that in an alternative to a biological implant that completely dissolves over time, the implant of the present invention may be a permanent implant. It is also noted that in an additional embodiment, the implant may alternatively be placed on a side of the disc or in the general vicinity of the concave or convex side of the spine.

The present invention relates to novel genetic markers associated with scoliosis, risk of developing scoliosis and risk of scoliosis curve progression, and methods and materials for determining whether a human subject has scoliosis, is at risk of developing scoliosis or is at risk of scoliosis curve progression.

Scoliosis in one instance refers to adolescent idiopathic scoliosis. In another instance scoliosis refers to either congenital, juvenile, syndromic or any other scoliosis condition. For the purpose of this invention the term scoliosis is used to describe any of these conditions.

The contribution or association of particular SNPs and/or SNP haplotypes with scoliosis phenotypes, such as adolescent idiopathic scoliosis, enables the SNPs of the present invention to be used to develop superior diagnostic tests capable of identifying individuals who express a detectable trait, such as scoliosis, as the result of a specific genotype, or individuals whose genotype places them at an increased or decreased risk of developing a detectable trait at a subsequent time as compared to individuals who do not have that genotype. For example, the presence of a single SNP known to correlate with scoliosis might indicate a odds ratio of 1.5 that an individual has or is at risk of developing scoliosis, whereas detection of five SNPs, each of which correlates with scoliosis, might indicate an odds ratio of 9.5 that an individual has or is at risk of developing scoliosis. To further increase the accuracy of diagnosis or predisposition screening, analysis of the SNPs of the present invention can be combined with that of other polymorphisms or other risk factors of scoliosis, such as Cobb angle, Risser sign, gender and age.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A method of treating a scoliotically curved spine in a patient being determined to be at risk of scoliosis curve progression comprising placing at least one of a growth stimulant, a medication, and a biological therapy on a concave side of said curve formed in said spine, wherein said biological therapy defines a dissolvable bone growth stimulant biological implant coated with a dissolvable coating, wherein determining said patient is at risk of scoliosis curve progression further defines a determination of genetic predisposition wherein DNA of said patient includes a plurality of genetic markers having an association with adolescent idiopathic scoliosis contained therein and wherein said risk is determined by performing logistic regression on said plurality of adolescent idiopathic scoliosis associated genetic markers.

2. The method of claim **1**, wherein said biological therapy comprises an implant of at least one of a Parathyroid hormone, a Fibroblast growth factor, an androgen, an Insulin-like Growth Factor, an Estrogen, a Transforming Growth Factor, and an inorganic phosphate.

3. The method of claim **1**, wherein said biological therapy defines an implant that is inserted into said patient by placing said biological therapy into an implantation apparatus and causing said biological therapy to move from said implantation apparatus into said patient.

4. The method of claim **3**, wherein said implantation apparatus defines a trocar.

5. The method of claim **1**, wherein said method includes at least one of the following steps comprising determining said patient is at risk of scoliosis curve progression in response to performing a calculation based on at least one scoliosis associated biological marker being detected in a biological sample of said patient, joining at least one mechanical implant to a first vertebra and to a second vertebra of the spine of said patient, and applying a brace to said patient.

6. The method of claim **5**, wherein said at least one scoliosis associated biological marker defines an adolescent idiopathic scoliosis associated biological marker, and wherein joining at least one mechanical implant to a first vertebra and to a second vertebra of said spine further defines joining a first fastener to a first scoliotic vertebra and a second fastener to a second scoliotic vertebra on a concave side of a curve formed in a scoliotic spine, joining at least one mechanical implant with said first fastener and said second fastener, and expanding said at least one mechanical implant between said first scoliotic vertebra and said second scoliotic vertebra such that a distraction force is provided between said first scoliotic vertebra and said second scoliotic vertebra, and wherein applying a brace to said patient further defines providing an external brace having no more than three principal load applying contact points; fitting said brace to said patient; and treating said spine of said patient by periodic brace adjustments.

7. A method of treating an uninjured non-osteoarthritic osteophyte-free spine in a vertebrate patient having at least one scoliosis associated biological marker identified in DNA of said patient having an association with adolescent idiopathic scoliosis contained therein comprising performing logistic regression on said adolescent idiopathic scoliosis associated biological marker; and placing at least one of a growth stimulant, a growth inhibitor, a medication, and a biological therapy proximate said spine of said patient, wherein said biological therapy defines at least one of a dissolvable bone growth stimulant implant coated with a dissolvable coating and a dissolvable bone growth inhibitor implant coated with a dissolvable coating, wherein said growth promoting biological implant is inserted between a first scoliotic vertebra and a second scoliotic vertebra on concave side of a curve of said spine, and wherein said growth inhibiting biological implant is inserted between said first scoliotic vertebra and said second scoliotic vertebra on convex side of said curve of said spine.

8. The method of claim **7**, wherein said at least one biological therapy defines at least one of a bone growth promoting implant and a growth inhibiting implant.

9. The method of claim **7**, wherein said at least one biological therapy includes at least one bone growth promoting implant and at least one bone growth inhibiting implant.

10. The method of claim **7**, wherein said spine includes a curve formed therein.

11. The method of claim **7**, wherein said spine defines a scoliotic spine.

12. The method of claim 7, wherein said at least one biological therapy defines a bone growth promoting implant, and wherein said spine includes a curve formed therein, and wherein said at least one bone growth promoting implant is inserted proximate a concave side of said curve of said spine.

13. The method of claim 12, wherein said spine defines a scoliotic spine, and wherein said biological therapy is inserted between a first scoliotic vertebra and a second scoliotic vertebra on said concave side of said curve of said scoliotic spine.

14. The method of claim 12, wherein said spine defines a scoliotic spine.

15. The method of claim 7, wherein said at least one biological therapy includes at least one bone growth promoting implant and at least one bone growth inhibiting implant, and wherein said spine includes a curve formed therein, and wherein said at least one bone growth promoting implant is inserted proximate a concave side of said curve of said spine, and wherein said at least one bone growth inhibiting implant is inserted proximate a convex side of said curve of said spine.

16. The method of claim 15, wherein said spine defines a scoliotic spine.

17. The method of claim 7, wherein said biological therapy comprises an implant of at least one of a Parathyroid hormone, a Fibroblast growth factor, an androgen, an Insulin-like Growth Factor, an Estrogen, a Transforming Growth Factor, an inorganic phosphate, and an anti-metabolite.

18. The method of claim 7, wherein said biological therapy defines an implant that is inserted into said patient by placing said biological therapy into an implantation apparatus and causing said biological therapy to move from said implantation apparatus into said patient.

19. The method of claim 18, wherein said implantation apparatus defines a trocar.

20. The method of claim 7, wherein said method includes at least one of the following steps comprising determining said patient is at risk of scoliosis development or scoliosis curve progression, joining at least one mechanical implant to a first vertebra and to a second vertebra of said spine, and applying a brace to said patient.

21. The method of claim 20, wherein determining said patient is at risk of scoliosis development or scoliosis curve progression further defines the result of a screening test wherein a scoliosis related condition risk value is derived by performing a calculation based on at least one adolescent idiopathic scoliosis associated biological marker being detected in a biological sample of said patient, and wherein joining at least one mechanical implant to a first vertebra and to a second vertebra of said spine further defines joining a first fastener to a first scoliotic vertebra and a second fastener to a second scoliotic vertebra on a concave side of a curve formed in a scoliotic spine, joining at least one mechanical implant with said first fastener and said second fastener, and expanding said at least one mechanical implant between said first scoliotic vertebra and said second scoliotic vertebra such that a distraction force is provided between said first scoliotic vertebra and said second scoliotic vertebra, and wherein applying a brace to said patient further defines providing an external brace having no more than three principal load applying contact points; fitting said brace to said patient; and treating said spine of said patient by periodic brace adjustments.

22. A method of treating a scoliotic spine in a vertebrate patient being determined to be at risk of spine curve progression in response to performing a calculation based on at least one scoliosis associated biological marker being detected in a biological sample of said patient comprising placing at least one of a growth stimulant, a growth inhibitor, a medication, and a biological therapy proximate said scoliotic spine of said patient, wherein said at least one biological therapy includes at least one bone growth promoting implant and at least one bone growth inhibiting implant, wherein said bone growth promoting implant defines at least one of a dissolvable bone growth stimulant coated with a dissolvable coating and said bone growth inhibiting implant defines at least one of a dissolvable bone growth inhibitor coated with a dissolvable coating, wherein said spine includes a curve formed therein, wherein said at least one bone growth promoting implant is inserted proximate a concave side of said curve of said spine, and wherein said at least one bone growth inhibiting implant is inserted proximate a convex side of said curve of said spine; and joining at least one mechanical implant to a first vertebra and to a second vertebra of said spine, and applying a brace to said patient.

23. The method of claim 22, wherein said at least one biological therapy defines at least one of a bone growth promoting implant and a growth inhibiting implant.

24. The method of claim 22, wherein said at least one biological therapy includes at least one bone growth promoting implant and at least one bone growth inhibiting implant.

25. The method of claim 22, wherein said at least one biological therapy defines a bone growth promoting implant, and wherein said spine includes a curve formed therein, and wherein said at least one bone growth promoting implant is inserted proximate a concave side of said curve of said spine.

26. The method of claim 22, wherein said biological therapy is inserted on a concave side of a curve formed in said scoliotic spine.

27. The method of claim 22, wherein said biological therapy comprises an implant of at least one of a Parathyroid hormone, a Fibroblast growth factor, an androgen, an Insulin-like Growth Factor, an Estrogen, a Transforming Growth Factor, an inorganic phosphate, and an anti-metabolite.

28. The method of claim 22, wherein said biological therapy defines an implant that is inserted into said patient by placing said biological therapy into an implantation apparatus and causing said biological therapy to move from said implantation apparatus into said patient.

29. The method of claim 28, wherein said implantation apparatus defines a trocar.

30. The method of claim 22, wherein said at least one scoliosis associated biological marker defines an adolescent idiopathic scoliosis associated biological marker, and wherein joining at least one mechanical implant to a first vertebra and to a second vertebra of said spine further defines joining a first fastener to a first scoliotic vertebra and a second fastener to a second scoliotic vertebra on a concave side of a curve formed in a scoliotic spine, joining at least one mechanical implant with said first fastener and said second fastener, and expanding said at least one mechanical implant between said first scoliotic vertebra and said second scoliotic vertebra such that a distraction force is provided between said first scoliotic vertebra and said second scoliotic vertebra, and wherein applying a brace to said patient further defines providing an external brace having no more than three principal load applying contact points; fitting said brace to said patient; and treating said spine of said patient by periodic brace adjustments.

31. The method of claim 22, wherein determining said patient is at risk of scoliosis curve progression further defines a determination of genetic predisposition wherein the DNA of said patient includes a plurality of genetic markers having an association with adolescent idiopathic scoliosis contained therein and wherein said risk is determined by performing

logistic regression on said plurality of adolescent idiopathic scoliosis associated genetic markers.

32. A method of implanting a biological implant comprising selecting a vertebrate patient having plurality of adolescent idiopathic scoliosis associated genetic markers in the DNA of said patient; determining said patient is at risk of scoliosis development or scoliosis curve progression, wherein determining said patient is at risk of scoliosis curve progression further defines performing logistic regression on said plurality of scoliosis associated genetic markers; implanting said biological implant into said patient, wherein said biological implant defines at least one of a dissolvable bone growth stimulant coated with a dissolvable coating and a dissolvable bone growth inhibitor coated with a dissolvable coating, wherein the spine of said patient defines a scoliotic spine, and wherein said growth promoting biological implant is inserted between a first scoliotic vertebra and a second scoliotic vertebra on concave side of a curve of said scoliotic spine, and wherein said growth inhibiting biological implant is inserted between said first scoliotic vertebra and said second scoliotic vertebra on convex side of said curve of said scoliotic spine; and joining at least one mechanical implant to a first vertebra and to a second vertebra of the spine of said patient, and applying a brace to said patient.

33. The method of claim **32**, wherein said biological implant defines a bone growth modulating biological implant.

34. The method of claim **32**, wherein said biological implant is inserted proximate the spine of said patient.

35. The method of claim **32**, wherein said at least one biological implant defines at least one of a bone growth promoting implant and a growth inhibiting implant.

36. The method of claim **32**, wherein said at least one biological implant includes at least one bone growth promoting implant and at least one bone growth inhibiting implant.

37. The method of claim **32**, wherein the spine of said patient includes a curve formed therein.

38. The method of claim **32**, wherein the spine of said patient defines a scoliotic spine.

39. The method of claim **32**, wherein said at least one biological implant defines a bone growth promoting implant, and wherein the spine of said patient includes a curve formed therein, and wherein said at least one bone growth promoting implant is inserted proximate a concave side of said curve of said spine.

40. The method of claim **39**, wherein said spine defines a scoliotic spine, and wherein said biological implant is inserted between a first scoliotic vertebra and a second scoliotic vertebra on said concave side of said curve of said scoliotic spine.

41. The method of claim **39**, wherein said spine defines a scoliotic spine.

42. The method of claim **32**, wherein said at least one biological implant includes at least one bone growth promoting implant and at least one bone growth inhibiting implant, and wherein the spine of said patient includes a curve formed therein, and wherein said at least one bone growth promoting implant is inserted proximate a concave side of said curve of said spine, and wherein said at least one bone growth inhibiting implant is inserted proximate a convex side of said curve of said spine.

43. The method of claim **42**, wherein said spine of said patient defines a scoliotic spine.

44. The method of claim **32**, wherein said biological implant comprises at least one of a Parathyroid hormone, a Fibroblast growth factor, an androgen, an Insulin-like Growth Factor, an Estrogen, a Transforming Growth Factor, an inorganic phosphate, and an anti-metabolite.

45. The method of claim **32**, wherein said biological implant is inserted into said patient by placing said biological implant into a biological implantation apparatus and causing said biological implant to move from said biological implantation apparatus into said patient.

46. The method of claim **45**, wherein said biological implantation apparatus defines a trocar.

47. The method of claim **32**, wherein determining said patient is at risk of scoliosis development or scoliosis curve progression further defines the result of a screening test wherein a scoliosis related condition risk value is derived by performing a calculation based on at least one scoliosis associated biological marker being detected in a biological sample of said patient, and wherein joining at least one mechanical implant to a first vertebra and to a second vertebra of said spine further defines joining a first fastener to a first scoliotic vertebra and a second fastener to a second scoliotic vertebra on a concave side of a curve formed in a scoliotic spine, joining at least one mechanical implant with said first fastener and said second fastener, and expanding said at least one mechanical implant between said first scoliotic vertebra and said second scoliotic vertebra such that a distraction force is provided between said first scoliotic vertebra and said second scoliotic vertebra, and wherein applying a brace to said patient further defines providing an external brace having no more than three principal load applying contact points; fitting said brace to said patient; and treating said spine of said patient by periodic brace adjustments.

48. A method of treating a vertebrate subject having at least one scoliosis associated biological marker identified in the DNA of said subject, comprising placing at least one of a growth stimulant, a growth inhibitor, a medication, and a biological therapy on a concave side of a curve formed in the spine of said subject, joining at least one mechanical implant to a first vertebra and to a second vertebra of the spine of said subject, and applying a brace to said subject, wherein said scoliosis associated biological marker defines an adolescent idiopathic scoliosis associated biological marker, and wherein said biological therapy defines at least one dissolvable bone growth stimulant biological implant coated with a dissolvable coating and at least one dissolvable bone growth inhibiting biological implant coated with a dissolvable coating, and wherein said at least one dissolvable bone growth stimulant biological implant coated with a dissolvable coating is inserted proximate a concave side of said curve of said spine, and wherein said dissolvable bone growth inhibiting biological implant coated with a dissolvable coating is inserted proximate a convex side of said curve of said spine.

49. The method of claim **48**, wherein said scoliosis associated biological marker defines an adolescent idiopathic scoliosis associated biological marker.

50. The method of claim **48**, wherein said biological therapy defines at least one of a dissolvable bone growth stimulant biological implant coated with a dissolvable coating and a dissolvable bone growth inhibiting biological implant coated with a dissolvable coating.

51. The method of claim **50**, wherein said bone growth stimulant comprises at least one of a Parathyroid hormone, a Fibroblast growth factor, an androgen, an Insulin-like Growth Factor, an Estrogen, a Transforming Growth Factor, and an inorganic phosphate.

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